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(11) EP 1 266 631 A1

(12)

#### **EUROPEAN PATENT APPLICATION**

(43) Date of publication:

18.12.2002 Bulletin 2002/51

(51) Int Cl.7: A61B 17/12

(21) Application number: 02254120.5

(22) Date of filing: 13.06.2002

(84) Designated Contracting States:

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR

Designated Extension States: **AL LT LV MK RO SI** 

(30) Priority: 13.06.2001 US 880506

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(54) Embolic coil

(57) A coil for occluding the vasculature of a patient. The coil has a textured surface which provides improved platelet adhesion compared to a non-textured surface, to promote clotting. The coil comprises a platinum-tungsten alloy wire and the texturing is performed by abra-

sion or sandblasting to provide substantially uniform roughness comprising pockets having diameters of about 0.125  $\mu m$  to about 50  $\mu m$  and depths of about 0.25  $\mu m$  to about 20  $\mu m$ .

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#### Description

[0001] The present invention concerns an embolic coil. The coil of the invention can be used to occlude the vasculature of a patient.

[0002] A known technique for treating a brain aneurysm of a patient includes the placement of embolic coils within the aneurysm. To this end, a catheter is introduced into the vessel leading to the aneurysm, and embolic coils are delivered to pack and fill the aneurysm. Ordinarily, a deployment system is used to deliver the coils, via the catheter, to the aneurysm, such as the deployment system disclosed in US-6113622.

[0003] The embolic coils act to reduce the blood flow inside of the aneurysm. Typically the embolic coils provide a mechanical blockage to the blood flow in the aneurysm. In this manner, the stagnation of blood that is obtained prevents the blood flow from rupturing the aneurysm. However, such stagnation forms a thrombus inside the aneurysm, that eventually can get resorbed.

[0004] The present invention provides a technique for blocking blood flow with the addition of platelet adhesion to the embolic coils. This allows tissue to grow, and the thrombus that forms, instead of being resorbed, has the ability to be organized into fibrous scar tissue. Such fibrous scar tissue achieves long term healing of the aneurysm in contrast to the use of embolic coils that can move around with the result that the formed thrombus may be resorbed.

[0005] The coil of the invention is useful for occluding the vasculature of a patient. In addition to embolising an aneurysm, the coil can also be used for embolising a vessel for vessel sacrifice; for reducing or blocking blood flow to an arterial-venous malformation or to a fistula; and for blocking blood flow to tumours.

[0006] In one aspect, the present invention provides an embolic coil formed of wire and having a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

[0007] A coil according to the invention is introduced into a patient's vasculature, preferably together with a plurality of other similar embolic coils. The textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

**[0008]** The adhesion of platelets to the coil of the invention encourages tissue formation and can prevent a coil from moving around within an aneurysm.

[0009] Preferably, the surfaces of the embolic coils can be textured by abrasion or sandblasting. Preferably, the embolic coil comprises a platinum-tungsten alloy wire. Preferably, the embolic coil has a substantially uniform roughness comprising pockets having diameters of between about 0.125  $\mu m$  (microns) and about 50  $\mu m$  (microns) and depths between about 0.25  $\mu m$  (microns) to 20  $\mu m$  (microns).

[0010] In another aspect, the invention provides an embolic coil formed of a platinum alloy wire and having

a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesions compared to a non-textured surface to promote clotting, the coil including a proximal portion and a distal portion, in which the proximal portion is relatively smooth and said textured surface is on said distal portion, the textured portion having substantially uniform roughness comprising pockets having diameters between about 0.125  $\mu m$  (microns) and about 50  $\mu m$  (microns) and depths between about 0.25  $\mu m$  (microns) and about 20  $\mu m$  (microns).

[0011] The present invention will now be described by way of example with reference to the accompanying drawings, in which:

Fig. 1 is a view of an embolic coil constructed in accordance with the principles of the present invention.

Fig. 2 is a diagram of a patient's brain aneurysm having the coils of the present invention implanted therein.

Fig. 3 is a photomicrograph, enlarged 233x, showing a portion of an embolic coil with a smooth surface, prior to texturing.

Fig. 4 is a photomicrograph, enlarged 233x, showing a similar portion of an embolic coil as the Fig. 3 portion, but with texturing.

Fig. 5 is a photomicrograph, enlarged 3880x, showing a portion of an embolic coil with a smooth surface, prior to texturing.

Fig. 6 is a photomicrograph, enlarged 3880x, showing a similar portion of an embolic coll as the Fig. 5 portion, but with texturing.

[0012] Referring to the drawings, Fig. 1 shows an embolic coil constructed in accordance with the principles of the present invention. Embolic coil 10 is formed by winding a platinum-tungsten alloy wire into a helical configuration. In the illustrative embodiment, the diameter of the wire is generally in the range of about 0.0038 to 0.20 mm (0.0015 to 0.008 inches). The outside diameter of the coil 10 is preferably in the range of about 0.15 to 1.40 mm (0.006 to 0.055 inches). The embolic coil 10 shown in Fig. 1 may be straight or may take the form of various configurations, including the form of a helix, a random shape configuration, or a coil within a coil configuration.

[0013] The details of construction of an example embolic coil, although no limitation is intended, is disclosed in US-6063100.

[0014] With the helical wound coil as illustrated in Fig. 1, the coil is provided with a seal plug 12 at its distal end and another seal plug 14 at its proximal end. Seal plugs 12 and 14 serve to prevent the flow of fluid through the lumen of the coil 10.

[0015] A suitable material from which the coil can be formed is a platinum-tungsten alloy comprising 92% platinum and 8% tungsten. Preferably, the outer surface

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of the coil is textured by abrasion or sandblasting. To this end, alumina particles having a diameter of 50  $\mu m$  (micron) are used to texture the surface of the wire that is used to form the coils, prior to the formation of the helical coils. It has been found that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization.

[0016] The texturization provides a uniform roughness comprising pockets having diameters of between about 0.125  $\mu$ m (microns) and about 50  $\mu$ m (microns) and depths of between about 0.25  $\mu$ m (microns) and about 20  $\mu$ m (microns). The roughness is uniform throughout the coil except if the coil is used with a detachment system such as disclosed in US-6113622 or US-6063100, a proximal portion of the coil is not textured in order for it to have a proper seal with a gripper so that it can released easily.

[0017] Fig. 2 is a diagrammatic view of a patient's vessel 16 leading to an aneurysm 18 into which a number of embolic coils 10 have been introduced. The coils are introduced in a manner known in the art, by introducing a catheter into the vessel 16, then introducing a deployment device via the catheter to deliver the embolic coils, one by one, to the aneurysm 18.

[0018] SEM micrographs of the non-textured vs. textured coils are provided in Figs. 3-6. Referring to Fig. 3, a portion of a non-textured coil is shown in a micrograph having an enlargement of 233x. Fig. 4 shows a similar coil with a 233x enlargement, but with texture that has been provided by sandblasting as disclosed above. Fig. 5 is a greatly enlarged micrograph, having an enlargement of 3880x, of the coil sample of Fig. 3 and Fig. 6 is a greatly enlarged micrograph having an enlargement of 3880x, of the coil sample of Fig. 5.

[0019] Testing was conducted using radio-labelled platelets to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increased in the platelet deposition of about fifty percent over the non-texture coils. [0020] It can be seen that by using embolic coils that have been textured, there is superior platelet adhesion which promotes clotting and subsequent endothelialization. A texturing technique has been disclosed that is simple and does not require expensive or elaborate equipment to modify the coils. In the illustrative embodiment the texturing technique does not require coating or ion implantation, thereby avoiding the importation of any new materials to the coil that would require new biocompatability testing.

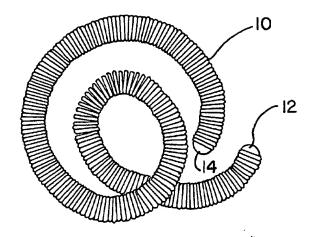
#### Claims

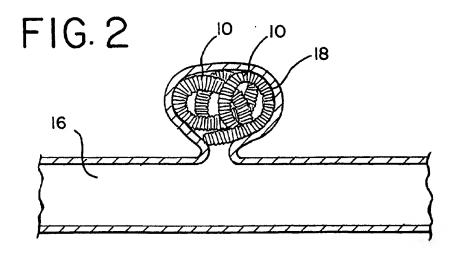
 An embolic coil formed of wire and having a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

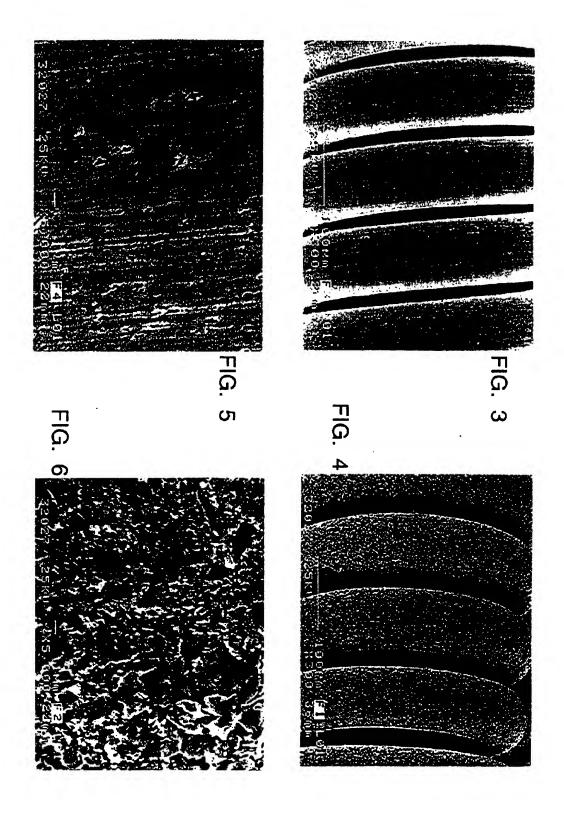
- An embolic coil as defined in claim 1, in which said embolic coil comprises a platinum-tungsten alloy wire.
- An embolic coil as defined in claim 1, in which said embolic coil includes a proximal portion and a distal portion; said proximal portion being relatively smooth and said textured surface being on said distal portion.
- An embolic coil as defined in claim 1, in which said embolic coil has substantially uniform roughness comprising pockets having diameters between about 0.125 μm (microns) and about 50 μm (microns).
- An embolic coil as defined in claim 4, in which said pockets have depths of between about 0.25 μm (microns) and about 20 μm (microns).
- 6. An embolic coil formed of a platinum alloy wire and having a textured surface which, when said embolic coil is implanted in a patient's vasculature, provides improved platelet adhesions compared to a non-textured surface to promote clotting, the coil including a proximal portion and a distal portion, in which the proximal portion is relatively smooth and said textured surface is on said distal portion, the textured portion having substantially uniform roughness comprising pockets having diameters between about 0.125 μm (microns) and about 50 μm (microns) and depths between about 0.25 μm (microns) and about 20 μm (microns).

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FIG.I









#### **EUROPEAN SEARCH REPORT**

Application Number EP 02 25 4120

	Citation of class amount with in-	lostion where enemarists	Relevant	01 400100 1 71011 07 71	
Category	Citation of document with ind of relevant passage		to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)	
Х	FR 2 696 636 A (BALT 15 April 1994 (1994-		1	A61B17/12	
γ	* page 1, line 31 -		2		
Y	US 5 911 731 A (DOAN 15 June 1999 (1999-0 * column 2, paragrap * column 4, paragrap figure 10B *	2			
A	US 6 024 754 A (ENGE 15 February 2000 (20 * column 2, paragrap paragraph 3 * * column 6, paragrap paragraph 4 *	00-02-15) h 5 - column 3,	1-6		
A	SHAKEEL (GB); REIDY 22 January 1998 (199 * page 3, paragraph	MEDICAL LTD ;QURESHI JOHN (GB); ANSON AN) 8-01-22) 6 - page 4, paragraph		TECHNICAL FIELDS	
	3 * * page 6, paragraph 3 *	2 - page 6, paragraph		A61B A61F	
	•				
	The present search report has be	en drawn up for all claims			
Place of search MUNICH		Date of completion of the search 22 October 2002	Lun	Examiner  Lundblad, H	
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O : non-written disclosure P : Intermediate document		& : member of the s	<ul> <li>inember of the same patent family, corresponding document</li> </ul>		

#### ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 02 25 4120

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

22-10-2002

Patent documer cited in search rep		Publication date		Patent family member(s)	Publication date
FR 2696636	A	15-04-1994	FR	2696636 A	1 15-04-1994
US 5911731	A	15-06-1999	US CA EP JP JP EP JP US US	5645558 A 2186768 A 0765636 A 3024071 B 9168541 A 0743047 A 9094300 A 6090125 A 5766219 A	1 30-03-1997 2 02-04-1997 2 21-03-2006 30-06-1997 2 20-11-1996 08-04-1997
US 6024754	А	15-02-2000	US	5749894 A	12-05-1998
WO 9802100	Α	22-01-1998	AU EP WO JP US US	3550897 A 0915678 A 9802100 A 2000514336 T 2002099437 A 6432134 B	1 19-05-1999 1 22-01-1998 31-10-2000 1 25-07-2002

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